EFFECTIVE DATE: 05|23|2013
POLICY LAST UPDATED: 01|17|2017

OVERVIEW
This policy documents the criteria and documentation requirements for immunoassay testing (i.e., presumptive testing, screening) and definitive testing (i.e., confirmatory testing) drug toxicology tests.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Immunoassay testing (i.e., presumptive testing, screening) and definitive testing (i.e., confirmatory testing) urine drug toxicology tests are covered.

Medical records must document the medical necessity of billed services and must be made available to Blue Cross & Blue Shield of Rhode Island (BCBSRI) upon request. See the Background section of this policy for documentation requirements.

Presumptive testing is not eligible for reimbursement as described below:
- Testing as required for or as part of participation in a substance abuse program
- Routine testing (i.e., testing at every visit)
- Testing ordered by or for third parties for the sole purpose of meeting the requirements of a third party

Definitive testing is not eligible for reimbursement as described below:
- Routine quantitative drug testing (i.e., testing at each visit)
- Quantitative testing when qualitative testing is clinically appropriate and meets clinical needs
- Routine confirmatory testing in the absence of an unexpected positive finding or an unexpected negative finding
- Testing ordered by or for third parties for the sole purpose of meeting the requirements of a third party

In outpatient pain management and substance abuse treatment, hair drug testing and oral fluid drug testing are considered not medically necessary. The current published evidence does not permit conclusions on the impact of hair or oral fluid drug testing on clinical outcomes.

COVERAGE
Benefits may vary. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable laboratory benefits/coverage.

BACKGROUND

Immunoassay Testing (Also called Qualitative Testing, Presumptive Testing, Screening)
These tests can be performed either in a laboratory or at the point of service. Immunoassay tests are based on the principle of competitive binding and use antibodies to detect a particular drug or drug metabolite in a urine sample. With competitive binding, a fixed amount of a labeled drug is added to the urine sample, and the drug or metabolite in the sample competes with the labeled drug for binding sites on the antibody. The amount of labeled antigen that binds with the antibody is inversely proportional to the amount of the drug or metabolite in the sample.

Immunoassay tests vary in the type of compounds they can detect. Some detect specific drugs and may fail to recognize similarly structured drugs within the same class. Other immunoassays identify only classes of drugs and thus results cannot be used to determine which drug a patient is taking. For example, a positive result to an opiate immunoassay can be due to morphine or hydromorphone. The degree of cross-reactivity, i.e., an antibody's reactivity with a compound other than the target of the test, varies widely among immunoassays.

Immunoassay findings are generally reported qualitatively as either positive (drug level above a prespecified threshold) or negative (drug level below a prespecified threshold). Raising or lowering the threshold thus changes the proportion of positive tests. A negative test is interpreted as a level below the threshold and does not necessarily mean that the drug or metabolite is absent.

Immunoassays generally have a rapid turnaround time, within minutes for onsite tests and 1 to 4 hours for laboratory-based tests.

Presumptive urine drug testing to verify compliance with treatment or identify disclosed drug use or abuse is considered medically necessary as part of a routine monitoring program. Presumptive urine drug testing is considered medically necessary under the following conditions:

- An individual is receiving treatment for chronic pain with prescription opioid or other potentially abused medications; or
- An individual is undergoing treatment for or monitoring for relapse of opioid addiction or substance abuse; or
- Abuse of non-prescribed medications or illegal substances is suspected; or
- An individual is beginning a pain management program or substance abuse recovery program.

Medical records must document the medical necessity of billed services.

Specific Drug Identification
Confirmatory tests are always performed in a laboratory. Gas chromatography/mass spectrometry (GC/MS) is considered to be the criterion standard for confirmatory testing. This technique involves using GC to separate the analytes in a specimen and MS to identify the specific molecular structures of the drug and its metabolites. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Definitive quantitative tests can be used to confirm the presence of a specific drug identified by a screening test and can identify drugs that cannot be isolated by currently available immunoassays. Results are reported as the specific levels of substances detected in the urine. GC/MS generally requires specification of the drug or drugs to be identified. Alternatively, "broad spectrum screens" can be conducted. There is a several day turnaround time for GC/MS testing.

An issue with both types of UDT is the possibility of sample tampering to mask the presence of illegal drugs. A variety of products and techniques are available to patients, and can be as simple as drinking a large amount of water to dilute the sample. There are also commercial dilution and cleaning products, additives, and urine substitutes. Some of these techniques can be detected by visual inspection of the sample, e.g., color, or by onsite testing of sample characteristics including urine temperature, creatinine concentration, and specific gravity.

In addition, correct interpretation of urine drug testing (UDT) results is very important. Knowledge of drug metabolites is essential for accurate interpretation. Accurate interpretation of test results also requires knowledge of the drug manufacturing process. For example, due to manufacturing impurities, a small amount of hydrocodone may be present in urine samples from patients prescribed oxycodone. Thus, it would be acceptable to have this degree of hydrocodone if high amounts of oxycodone were also present.

There are various approaches to incorporating UDT into pain management and substance abuse treatment settings. Most commonly, patients undergo UDS before beginning treatment to verify current drug use. Some clinicians believe that UDS should be routinely used to establish baseline information about substance use, but the optimal frequency and interval of testing remains uncertain. A universal approach to screening may uncover more inappropriate use and may reduce patients' sense that testing is being performed due to a lack of trust. However, routine universal screening may place an unnecessary burden on the healthcare system and on the doctor-patient relationship. An alternative approach is selective testing of patients who are judged to be at increased risk for drug misuse.

Existing protocols vary for use of presumptive versus definitive tests. Some of these involve conducting routine confirmation of positive presumptive tests with definitive quantitative testing. Others use selective confirmation of positive presumptive tests, such as when an unexpected immunoassay result is not adequately explained by the patient. There is also a mixed approach, with routine conformation of presumptive tests only for drugs with poor-performing immunoassays.

Guidance Regarding Definitive, i.e., Confirmatory Testing
Specific situations for definitive drug testing may include, but are not limited to the following:

- Unexpected positive test inadequately explained by the patient
- Unexpected negative test (suspected medication diversion)
- Need for quantitative levels to compare with established benchmarks for clinical decision making

Definitive or confirmatory testing must be ordered on an individual basis by a medical provider directly caring for a member at the time of order and may not be ordered from "standing" orders, i.e., orders that provide for routine testing. Definitive testing must be ordered with an indication of the specific drug being confirmed, not as a comprehensive confirmatory panel.

According to Medicare instructions, drug testing providers performing validity testing on urine specimens utilized for drug testing should not separately bill the validity testing. For example, if a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed. Testing to confirm that a urine specimen is unadulterated is an internal control process that is not separately reportable.

Regulatory Status
Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Gas chromatography/mass spectrometry tests and some immunoassays are performed in laboratory settings. Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration (FDA) has chosen not to require any regulatory review of this test.

A CLIA waiver is available for use of certain point-of-care immunoassays. Tests eligible for a CLIA waiver are those considered to be simple, with low risk of error and low potential for harm. FDA is tasked with approving manufacturers' applications for test system waivers. There are commercially available CLIA-waived urine tests for drugs such as cocaine, methadone, morphine/opiates, and oxycodone. There are also commercially available hair testing tests such as Quest Diagnostics ELISA tests for amphetamines, opiates,

cocaine, marijuana metabolites, and phencyclidine. In addition, Omega Laboratories offers hair drug screening for cocaine and cocaine metabolites.
Several oral fluid drug test collection devices have been cleared for marketing by FDA through the 510(k) process. They include:

- Intercept™ Oral Fluid Drug Testing System (OraSure Technologies, Bethlehem, PA)
- Oral-Eze Saliva Collection System (Quest Diagnostics, Madison NJ)
- Quantisal® Oral Fluid Collection Device (Alere, Waltham, MA).

In addition to the oral fluid collection devices, FDA has cleared a number of assays for analysis of oral samples. For example, there are FDA-cleared assays for 9 drugs collected with the Intercept device. They are amphetamines, methamphetamine, cocaine/metabolite, opiates, marijuana/THC, phencyclidine, barbiturates, benzodiazepines, and methadone.

Oral Fluid Testing
The limited number of studies on the diagnostic accuracy of oral fluid testing compared with urine testing had variable findings. No studies were identified on the impact of oral fluid testing on health outcomes compared with UDT or no drug testing.

Hair Testing
Hair testing cannot detect recent drug use (ie, in the past few days). One study looked at this longer time frame in patients starting psychiatric treatment. It found a higher prevalence of drug use with hair testing versus UDT testing for most drugs; however, the implications of study findings for patients in pain management or substance abuse treatment is unclear. No studies were identified on the diagnostic accuracy of hair testing versus urine testing in patients with chronic pain or substance abuse. In addition, no studies were identified on the clinical utility of hair testing in pain management or substance abuse treatment.

Therefore, these services are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

BlueCHiP for Medicare and Commercial Products
Note: It is incorrect to bill creatinine, pH, specific gravity, aldehyde, chromate, oxidase, or any other test for specimen validity testing in addition to the drug testing codes. The code descriptions for the codes below include sample validation, if performed.
The following CPT/HCPCS codes are covered when payment guidelines are met:
80305 80306 80307 (New codes effective 1/1/2017)
G0477 G0478 G0479 (Codes deleted effective 12/31/2016)
G0480 G0481 G0482
G0483 G0659 (New code effective 1/1/2017)

The following CPT codes should not be used. Claims should be filed with one of the above HCPCS G codes for definitive testing
CPT range **80320 through 80377**
80184 83992

RELATED POLICIES

None

PUBLISHED

Provider Update, March 2017
Provider Update, October 2016
Provider Update, March 2016
Provider Update, July 2015

Provider Update, November 2013
Provider Update, June 2011
Provider Update, July 2008

REFERENCES

1. Manchikanti L, Malla Y, Wargo BW, et al. Comparative evaluation of the accuracy of immunoassay with liquid chromatography tandem mass spectrometry (LC/MS/MS) of urine drug testing (UDT) opioids and illicit drugs in chronic pain patients. Pain Physician. Mar-Apr 2011;14(2):175-187. PMID 21412372

2 Goldberg KC, Simel DL, Oddone EZ. Effect of an opioid management system on opioid prescribing and unscheduled visits in a large primary care clinic. J Clinical Outcomes Management. 2005;12:621-628. PMID

3 Dupouy J, Memier V, Catala H, et al. Does urine drug abuse screening help for managing patients? A systematic review. Drug Alcohol Depend. Mar 1 2014;136:11-20. PMID 24417964

4. Chutuape MA, Silverman K, Stitzer ML. Effects of urine testing frequency on outcome in a methadone take-home contingency program. Drug Alcohol Depend. Mar 1 2001;62(1):69-76. PMID 11173169

5. American society of Addiction Medicine (ASAM). Public Policy Statement On Drug Testing as a Component of Addiction Treatment and Monitoring Programs and in other Clinical Settings. http://www.asam.org/docs/publicy-policy-statements/1drug-testing---clinical-10-10.pdf?sfvrsn=0. Accessed November 9, 2016.

6. Manchikanti L, Atluri S, Trescot AM, et al. Monitoring opioid adherence in chronic pain patients: tools, techniques, and utility. Pain Physician. Mar 2008;11(2 Suppl):S155-180. PMID 1844363

7. Johnson-Davis KL, Sadler AJ, Genzen JR. A retrospective analysis of urine drugs of abuse immunoassay true positive rates at a national reference laboratory. J Anal Toxicol. Mar 2016;40(2):97-107. PMID 26668238

8. McDonell MG, Graves MC, West, II, et al. Utility of point-of-care urine drug tests in the treatment of primary care patients with drug use disorders. J Addict Med. May-Jun 2016;10(3):196-201. PMID 27159345

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.